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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,342	12/31/2003	Jeffry G. Weers	0190.00	7605

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EXAMINER	
CARTER, KENDRA D	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,342	WEERS ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-97* is/are pending in the application.

4a) Of the above claim(s) *97* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/22/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-96, in the reply filed on May 2, 2007 is acknowledged. The traversal is on the ground(s) that the search of potential art is simultaneously useful for Group I and Group II and thus does not create a serious burden to the Examiner. This is not found persuasive because of reasons stated in the previous office action and that the Groups are classified in separate classes and subclasses.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 98 has been renumbered to claim 97.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 18-20, 23-36, 38-40, and 43-72 and 74-76 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-25, 27-30, 35-44 of copending Application No. 11/187,757 ('757). Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Application '757 teaches a method for treating a patient suffering from a fungal infection of the lung, comprising administering to the patient a therapeutically effective

amount of a pharmaceutical formulation comprising a lipid matrix and at least one particle of an antifungal agent in the lipid matrix wherein the aerosolized (see claim 35) pharmaceutical formulation is for pulmonary administration (see claim 45) via inhalation (see claims 23 and 27). For clarification, the application '757 defines treating as providing prevention of a particular condition (see page 2, paragraph 26, lines 6-8). The lipid matrix comprises a phospholipid (see claim 7). The composition can be a dry powder that has a bulk density of less than 0.5 g/cm^3. The antifungal agent is amphotericin B (see claims 29 and 30). The amount of antifungal agent is at least twice the minimum inhibitory concentration of the antifungal agent for at least one week (see claim 35), three weeks or three months (see claims 39-42). Thus, determining the minimum inhibitory concentration is taught in application '757 because in order to administer twice the minimum inhibitory concentration, the minimum inhibitory concentration of the antifungal agent needs to be determined. The minimum inhibitory concentration is in the epithelial lining or the solid tissue of the lung (see claims 36 and 37), with a lung concentration at least 9 μg/g or in the range of 9 μg/g to 15 μg/g (see claims 43 and 44).

The application '757 does not teach a single dose or two doses of the pharmaceutical formulation during the first week of administration (applicant's claims 8 and 9). The two period administration wherein the antifungal agent is administered more frequently or at a higher dosage during the first period than during the second period is also not taught (see applicant's claims 10 and 44). Neither is the

administration comprising delivering the formulation periodically to maintain the antifungal agent lung concentration taught (see applicant's claim 13).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of '757 and the administration detailed above in the applicant's claims 8, 9, 10, 13 and 44 and determining the minimum inhibitory concentration of an antifungal agent for inhibiting pulmonary fungal growth because of the following: (1) the antifungal agent is administered for at least one week, three weeks or three months to maintain the twice the minimum inhibitory concentration (see claims 35 and 40-42); (2) it is within the art to administer a drug several times during a treatment. In order to treat the fungal infection the antifungal agent must be present in concentrations that are effective. Whether the drug is administered once, twice, or several times, the important factor is that twice the minimum inhibitory concentration is maintained in the lungs.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-96 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a pulmonary fungal infection , does not reasonably provide enablement for preventing a pulmonary fungal infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of treating and/or providing prophylaxis against a pulmonary fungal infection. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 1 is drawn to "a method of treating and/or providing prophylaxis against a pulmonary fungal infection, the method comprising: determining the minimum inhibitory concentration of an antifungal agent for inhibiting pulmonary fungal growth; and administering a aerosolized pharmaceutical formulation comprising the antifungal agent to the lungs of a patient; wherein a sufficient amount of the pharmaceutical formulation is administered to maintain for at least one week a target antifungal agent lung concentration of at least two times the determined minimum inhibitory concentration."

(2) The breadth of the claims:

Claims 1-96 embraces preventing pulmonary fungal infection. This reads on completely preventing all pulmonary fungal infections. The specification does not enable the complete prevention of pulmonary fungal infections.

(3) The state of the prior art:

The state of the art regarding preventing pulmonary fungal infections is very low or do not exist.

(4) The predictability or unpredictability of the art:

The predictability of completely preventing pulmonary fungal infections is relatively low. Therefore, to one skilled in the art, prevention of pulmonary fungal infections is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the prevention of pulmonary fungal infections is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that completely prevent pulmonary fungal infections. The specification states that the pharmaceutical formulation administered prophylactically comprising an antifungal agent is to reduce the likelihood of developing a fungal infection during an immunocomprised period (see page 11, lines 17-21). Reduction in the likelihood of developing a fungal infection does not provide complete prevention from an infection. One would need to show data that supported a patient never developed a fungal infection after administering the applicant's method. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on the complete prevention of all pulmonary fungal infections. As discussed above the specification fails to provide any support for completely preventing pulmonary fungal infections. Applicant fails to provide any

information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for treating pulmonary fungal infections, but not for preventing pulmonary fungal infections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-7, 11-21, 23-29, 33-41, 43, 45-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Tarara et al. (US 2006/0159625 A1).

Tarara et al. teaches a method of using a aerosolized pulmonary antifungal formulation comprising particularly with amphotericin B to treat antifungal infections, (see abstract lines 1-5 and claims 29 and 30; addresses claims 1, 11, 15, 23, 43, 49 and 52), comprising administering the formulation in an amount sufficient to maintain a target lung concentration of the antifungal agent that is at least twice the minimum inhibitory concentration of the antifungal agent for at least one week (see page 2, paragraph 17 in its entirety), three weeks or three months (see claims 39-42; addresses claims 4-7, 26-29, 47 and 48) . Thus, determining the minimum inhibitory concentration is inherently taught because in order to administer twice the minimum inhibitory concentration, the minimum inhibitory concentration of the antifungal agent needs to be determined. Also the administration of the formulation once per week (applicant's claim 45) is inherently taught because the formulation has at least twice the minimum inhibitory concentration for at least one week. Thus, in order for the formulation to be effective, after one week more of the formulation would be administered. The formulation comprises a lipid matrix, which comprises a phospholipid

(see claim 7 and 23; addresses claims 18, 19, 38 and 39). The composition can be a dry powder (see claim 25) that has a bulk density of less than 0.5 g/cm^3 and is activated by a dry powder inhaler (see page 2, paragraph 16, lines 3 and 6; addresses claims 16, 20, 36, 40 and 53). The minimum inhibitory concentration is in the epithelial lining or the solid tissue of the lung (see claims 36 and 37; addresses claims 2, 3, 24, 25, 46, and 47), with a lung concentration at least 9 μg/g or in the range of 9 μg/g to 15 μg/g (see claims 43 and 44; addresses claims 12-14, 23, 33-35, 50 and 51). Delivering the pharmaceutical formulation periodically to maintain the antifungal agent lung concentration within the target antifungal lung concentration range is inherently taught because the formulation is administered in an amount sufficient to maintain a target lung concentration of the antifungal agent that is at least twice the minimum inhibitory concentration of the antifungal agent (see page 2, paragraph 17 in its entirety). The particles of the formulation can assume various shapes and forms such as hollow an/or porous microstructures (see page 2, paragraph 24, lines 7-9; addresses claims 17 and 37). The particles are applied by pressurized air (i.e. propellant) from a dry powder dispersion unit (see page 2, paragraph 29, lines 10 and 13; addresses claims 21 and 41). The emitted dose is the delivery of the dry powder from an inhaler device after an actuation or dispersion event from a powder unit or reservoir (i.e. opening a valve to release the formulation; see page 3, paragraph 32, lines 1-3; addressing claims 21 and 41). The invention is not limited to specific administration regimes, drug delivery devices or the like, as such may vary (see page 2, paragraph 22, lines 1-3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(1) Claims 8-10, 30-32 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 2006/0159625 A1) as applied to claims 1-7, 11-21, 23-29, 33-41, 43 and 45-53 above.

The teaching of Tarara et al. (US 2006/0159625 A1) are as applied to claims 1-7, 11-21, 23-29, 33-41, 43 and 46-53 above.

Tarara et al. does not teach a single dose or two doses of the pharmaceutical formulation during the first week of administration (applicant's claims 8, 9, 30 and 31). The two period administration wherein the antifungal agent is administered more frequently or at a higher dosage during the first period than during the second period is also not taught (see applicant's claims 10, 32 and 44).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the dosing regimens of claims 8-10, 30-32 and 44 because Tarara et al. teaches that the invention is not limited to specific administration regimes, drug delivery devices or the like, as such may vary (see page 2, paragraph 22, lines 1-3).

(1) Claims 1-15, 23-35 and 43-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponikau (US 6,207,703 B1).

Ponikau teaches a pharmaceutical composition for treating an immune response to fungus in a mammal or a fungal related condition in the pulmonary anatomy comprising an effective dose of an anti-fungal agent (see column 10, lines 42, 43, 50-55) such as amphotericin B (see column 4, line 55 and claim 19;,) in an aerosol form as a powder or solution (see column 3, lines 65, 66 and column 4, lines 1; addresses claims 1, 11, 15, 20-23, 40-43, 49 and 52). The formulation contains about 0.01 ng to about 1000 mg of the antifungal agent (see column 4, lines 10-12; addresses claims

12-14, 23, 33-35, 50 and 51). The effective amount of a formulation can change or remain the same during an effective duration. The effective frequency of direct mucoadministration can be from about four times a day to about once every other week in some embodiments of the invention, or about twice a day in still other embodiments of the invention. In addition the effective frequency of direct mucoadministration can be greater than once a day, or greater than once a week. The effective duration can be greater than about 7, 14, 30, 60, 90 days (see column 4, lines 28-38; addresses claims 1-10, 23, 27-32, 43-45, and 48) or can vary from several days to several weeks, months or years (see column 25, lines 43 and 44). A typical effective amount can be any amount greater than or equal to the minimum inhibitory concentration for the fungal organism, and such amounts can be determined for individual antifungal agents using commonly available or easily ascertainable information involving antifungal effectiveness concentrations (see column 24, lines 10-12 and lines 21-23; addresses claims 1, 23 and 43). Direct mucoadministration to the lung airways can include inhalations or nasal sprays provided that the administered agent contacts lung airway mucus prior to crossing epithelium (see column 28, lines 9-12). Any device can be used to administer the agent to the lung airway including inhaler, nebulizer, aerosol canister, spray can, and mask (see column 28, lines 17-20).

Ponikau does not specifically teach that the minimum inhibitory concentration is in the epithelial lining or the solid tissue of the lung (claims 2, 3, 24, 25, 46 and 47).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Ponikau and the minimum inhibitory concentration is in the epithelial lining or the solid tissue of the lung because Ponikau teaches the following: (1) direct mucoadministration to the lung airways or pulmonary anatomy can include inhalations or nasal sprays provided that the administered agent contacts lung airway mucus prior to crossing epithelium (see column 28, lines 9-12 and see column 10, lines 42, 43, 50-55); and (2) A typical effective amount can be any amount greater than or equal to the minimum inhibitory concentration for the fungal organism, and such amounts can be determined for individual antifungal agents using commonly available or easily ascertainable information involving antifungal effectiveness concentrations (see column 24, lines 10-12 and lines 21-23).

(2) Claims 16, 20, 36, 40 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponikau (US 6,207,703 B1) as applied to claims 1-15, 20, 23-35, 40, and 43-52 above in view of Weickert et al. (US 2002/0177562 A1).

Ponikau teachings are as applied to claims 1-15, 20, 23-35, 40, and 43-52 above.

Ponikau does not teach a bulk density of less than 0.5 g/cm^3 or a dry formulation.

Weickert et al. teaches a composition for oral inhalation to the lung that demonstrates superior aerosol properties in the treatment of pulmonary fungal infections (see abstract, lines 2-3, 5 and 6). The composition comprise an antifungal dry powder preferably amphotericin B (see page 5, paragraph 66, lines 1, 4, 5, and 9). The powder typically possess a bulk density ranging from about 0.05 to 10 g/cm^3 (see page 10, paragraph 113, lines 1 and 2).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Ponikau and a bulk density of less than 0.5 g/cm^3 or a dry formulation because Weickert et al. teaches the following: (1) an antifungal dry powder composition comprising preferably amphotericin B (see page 5, paragraph 66, lines 1, 4, 5, and 9), with a bulk density ranging from about 0.05 to 10 g/cm^3 (see page 10, paragraph 113, lines 1 and 2); and (2) the composition is inhaled to the lungs and demonstrates superior aerosol properties in the treatment of pulmonary fungal infections (see abstract, lines 2-3, 5 and 6). Thus, it would be beneficial for the methods and compositions of Ponikau to be dry and have a specific bulk density.

(3) Claims 17-19 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponikau (US 6,207,703 B1) as applied to claims 1-15, 20, 23-35, 40, and 43-52 above in view of Unger (US 2001/0018072 A1).

Ponikau teachings are as applied to claims 1-15, 20, 23-35, 40, and 43-52 above.

Ponikau does not teach hollow and/or porous particles or a matrix material that comprises one or more phospholipids.

Unger teaches a solid porous matrix comprising a surfactant, such as phospholipids (see page 2, paragraph 19, lines 6 and 8) in combination with a bioactive agent (see abstract, lines 1 and 2), such as antifungal agents amphotericin B (see page 16, column 1, lines 19-21 and claim 27). The composition can be applied pulmonarily via inhalation by delivery of an aerosol (see page 35, paragraph 291, lines 13, 14, and 16). The invention is useful in delivering bioactive agents to a patient's lungs (see page 36, paragraph 297, lines 1 and 2).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Ponikau and a matrix material that comprises one or more phospholipids because Unger teaches the following: (1) a solid porous matrix comprising a surfactant, such as phospholipids (see page 2, paragraph 19, lines 6 and 8) in combination with a bioactive agent (see abstract, lines 1 and 2), such as antifungal agents amphotericin B (see page 16, column 1, lines 19-21 and claim 27); and (2) The invention is useful in delivering bioactive agents to a patient's lungs (see page 36, paragraph 297, lines 1 and 2).

(4) Claims 21 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponikau (US 6,207,703 B1) as applied to claims 1-15, 20, 23-35, 40, and 43-52 above in view of Johnson (US 5,126,123).

Ponikau teachings are as applied to claims 1-15, 20, 23-35, 40, and 43-52 above.

Ponikau does not teach a propellant wherein the administration comprises aerosolizing the amphotericin B by opening a valve to release the pharmaceutical formulation.

Johnson teaches aerosol inhalation drug formulations comprising one or more drugs in propellant (see abstract in its entirety). Drugs useful in this invention include those drugs adaptable to inhalation administration, for example, respiratory and antifungal drugs (see column 3, lines 34-37). For inhalation drugs, they are placed in a suitable container capable of withstanding the vapor pressures and fitted with a metering valve (see column 4, lines 37-46). Upon valve actuation, the amount of drug, surfactant and propellant delivered can be adjusted (see column 4, lines 52 and 53).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Ponikau and a propellant wherein the

administration comprises aerosolizing the amphotericin B by opening a valve to release the pharmaceutical formulation because Johnson teaches the following: (1) an aerosol inhalation drug formulations comprising respiratory and antifungal drugs in propellant (see abstract in its entirety and see column 3, lines 34-37); and (2) the formulation is placed in a suitable container capable of withstanding the vapor pressures and fitted with a metering valve that upon actuation, the formulation is released (see column 4, lines 37-46 and see column 4, lines 52 and 53). Thus, Johnson demonstrates a aerosol container with a valve that can be used in antifungal inhalation formulations.

(5) Claims 22 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponikau (US 6,207,703 B1) as applied to claims 1-15, 20, 23-35, 40, and 43-52 above in view of Lloyd et al. (US 5,544,646).

Ponikau teachings are as applied to claims 1-15, 20, 23-35, 40, and 43-52 above.

Ponikau does not teach a compressed gas and/or a vibrating member.

Lloyd et al. teaches a drug delivery device which creates aerosolized particles of a formulation comprised of drug in a carrier (i.e. liquid; see column 4, lines 29-31), such as water, ethanol and other carriers that do not adversely effect the drug or human lung tissue (see column 5, lines 46-49). The device allows drug delivery directly to the lungs

(see column 21, lines 60 and 61). The means of applying physical force to the formulation is through a vibration device (see claim 18).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Ponikau and a vibrating member because Lloyd et al. teaches the following: (1) a device that allows drug delivery directly to the lungs (see column 21, lines 60 and 61); (2) the drug is comprised of a drug in a carrier such as water, ethanol and other carriers that do not adversely effect the drug or human lung tissue (see column 5, lines 46-49); and (3) the device has a vibration device (see claim 18). Thus, Lloyd et al. demonstrates an aerosol device that can be used in the method of Ponikau.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER